THE NATIONAL QUALITY FORUM

Serious Reportable Events in Healthcare

A CONSENSUS REPORT

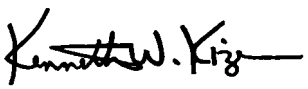
Foreword

Healthcare errors are a leading cause of morbidity and mortality in the United States. There is no national reporting of such occurrences, but a number of states require reporting of at least some types of healthcare errors and adverse events from at least some healthcare settings; however, there is no standard definition of what constitutes an error or adverse event. It is widely agreed that even where there is mandatory reporting of errors and adverse events, they are grossly underreported, due at least in part to ambiguity about what is to be reported.

As part of a comprehensive approach to improving patient safety, the Institute of Medicine (IOM) recommended that healthcare errors and adverse events be reported in a systematic manner. The federal government's Quality Interagency Coordination Task Force concurred with the IOM's recommendations for greater healthcare error and adverse event reporting, and the National Quality Forum was charged with identifying a core list of preventable, serious adverse events. This report has been prepared as part of fulfilling that charge.

Serious Reportable Events in Healthcare identifies 27 adverse events that are serious, largely preventable, and of concern to both the public and healthcare providers. The NQF encourages widespread adoption of this list of serious reportable events by states. If systematically utilized for reporting, analysis of the data will provide both caregivers and consumers with important information about the safety of healthcare and opportunities for improvement.

The report reflects the collective efforts of the NQF and its broad-based membership, the project's Steering Committee and its Ex Officio Special Advisory Panel of state officials, the Milbank Memorial Fund, the federal government, and many other interested stakeholders. We are grateful to all for their commitment to improving patient safety and healthcare quality.



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Serious Reportable Events in Healthcare

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Executive Summary

Lapses in patient safety are a major healthcare quality problem. Currently, few data exist that can provide reliable and consistent information on the number and type of the most serious preventable adverse events. Moreover, even when data are reported, such reporting varies widely by locale.

The objective of the National Quality Forum's (NQF) project on Serious Reportable Events in Healthcare is to establish agreement on a set of serious preventable adverse events that might form the basis for a national state-based event reporting system and that could lead to substantial improvements in patient care. The primary reason for identifying a standardized set of serious reportable events that would be reported on a mandatory basis would be to facilitate public accountability.

This report does not call for mandatory reporting. However, if a state has an existing system or establishes a reporting system, using the list of events recommended in this report would enable standardized data collection and reporting of such events within and across states. Whether and how states disclose these data to the public is a policy matter not discussed in this report.

The report identifies 27 serious adverse events that should be reported by all licensed healthcare facilities. The events are grouped into six categories: surgical, product or device, patient protection, care management, environmental, and criminal acts. Also identified in the report are standardized definitions of key terms. The NQF consensus list of serious reportable events is a starting point. Whether additional specification is needed for the events should be addressed as part of the pilot testing that the federal government intends to pursue.

Serious Reportable Events in Healthcare

Introduction

Lapses in patient safety are a major healthcare quality problem, and the occurrence of patient harm due to such lapses is remarkably common. A large majority of these lapses are preventable.

Recent studies suggest that most lapses in patient safety are the unintended consequences of a highly complex and imperfect healthcare delivery system in which individual minor mishaps occasionally combine to yield harmful, and sometimes disastrous, results.[1] Relatively few of these adverse events are related to professional misconduct or criminal acts.

Identifying where and when in the care process mishaps are most likely to occur and changing the processes of care to reduce the chance of harm requires reliable information about preventable adverse events. At present, few such data exist, since there is no standardized reporting system across states to provide reliable and consistent information on the number and type of the most serious preventable adverse events, including acts of misconduct.

The objective of the National Quality Forum's (NQF) project on Serious Reportable Events in Healthcare is to establish agreement on a set of serious preventable adverse events—sometimes called "never events"—that might form the basis for a national state-based event reporting system and that could lead to substantial improvements in the quality of patient care.[2] As described later in this document, a number of complementary activities to track adverse events and to identify and disseminate solutions for improving patient safety and

[1] Kohn LT, Corrigan JM, Donaldson MD, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

[2] This project was undertaken initially at the request of the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services (CMS). It was funded primarily by the Milbank Memorial Fund, with additional funds from AHRQ, CMS, and other entities as noted in the acknowledgments.

quality of care are needed. This report addresses one of these activities – the provision of standardized information on serious events for use by states in assuring accountability to the public. Appendix B presents additional background information, including more detail about the deliberations of the project's Steering Committee.

Purpose of the List

The primary reason for identifying a standardized set of serious reportable events that would be mandatorily reported is to facilitate public accountability for the occurrence of these adverse events in the delivery of healthcare. For this purpose, ***public accountability*** is considered to be the obligation or duty of specific individuals and/or institutions to make information about their actions or performance available to the public or a public agency (or its designee) that has responsibility for oversight and is answerable to the general public. Whether or how such data might be disclosed to the public after being reported to the responsible agency (e.g., in a de-identified manner or in aggregated regional reports naming individual healthcare providers, etc.) is a policy decision for the states, although at least some degree of public disclosure is recommended.

"The public expects healthcare professionals and providers and their organizations to take all necessary and appropriate steps to ensure that care is safe..."

The public expects healthcare professionals and providers and their organizations to take all necessary and appropriate measures to ensure that care is safe, and the public looks to government and other oversight authorities to make sure that this is done. The occurrence of a serious and presumptively preventable injury, such as amputating the wrong leg or transfusing the wrong type of blood, suggests but does not prove that a flaw exists in the healthcare organization's efforts to safeguard patients. It is reasonable for the public to expect an oversight body to investigate serious adverse events, such as those identified in this report, as part of its responsibility for ensuring patient safety. Privacy protections for both individuals and organizations are also an important responsibility.

Accountability entails both an obligation of healthcare organizations to report on their performance and of state or

oversight bodies to enforce compliance with accepted standards. Both parties have a responsibility and an obligation to use the information to improve patient safety. The NQF list of serious reportable events is intended to facilitate fulfillment of this obligation. Reporting, monitoring, and acting upon the reports constitutes a basic level of oversight.

Criteria for Including Events on the List

The core set of events described in this report is not intended to capture all events that might possibly be useful to report. Rather, the items on this list are events that are:

- of concern to both the public and healthcare professionals and providers;
- clearly identifiable and measurable, and thus feasible to include in a reporting system; and
- of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility.

To qualify for this core list of serious reportable events, an event must be:

Unambiguous, usually preventable, serious, and any of the following:

a. Adverse and/or

b. Indicative of a problem in a healthcare facility's safety systems and/or

c. Important for public credibility or public accountability.

The use of the term "usually preventable" recognizes that some of these events are not always avoidable, given the complexity of healthcare. The presence of an event on the list, therefore, is not an a priori judgment either of a systems failure or a lack of due care. Of note, the frequency with which an event occurs was considered but was not accepted as a criterion for inclusion of events on the list. Many serious events that are not frequent are cause for considerable concern when they occur.

An essential foundation for compiling this initial NQF list – and for updating the list in the future – is the definition of the terms that encompass the criteria. (See Box A.)

Box A – Definitions of Terms Used in Criteria

Event means a discrete, auditable, and clearly defined occurrence.

Adverse describes a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.

Preventable describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure.

Serious describes an event that results in death or loss of a body part, disability or loss of bodily function lasting more than seven days or still present at the time of discharge from an inpatient healthcare facility or, when referring to other than an adverse event, an event the occurrence of which is not trivial.

Unambiguous refers to an event that is clearly defined and easily identified.

List of Serious Reportable Events

Table 1 presents 27 serious reportable events that should be reported and investigated by all healthcare facilities as they occur; it is emphasized that individual incidents should be reported, not frequencies of events. The events are organized in six categories – five that relate to the provision of care (surgical, product or device, patient protection, care management, and environmental) and one category that includes four criminal events. These latter events involve illegal acts, or acts of misconduct, and are included because they could be indicative of an environment that is unsafe for patients. Although a healthcare facility cannot eliminate all risk of these events – e.g., of assault – it can take various preventive measures to reduce that risk. (See Table 1 on pages 6 and 7.)

By intent, this list of serious reportable events is relatively short and only includes clearly defined events. It was compiled with the understanding that a short and clearly defined list is more likely to be understood and widely utilized.

Finally, standardized terminology is essential if the NQF consensus list is to be implemented consistently by states and others. In compiling this list, three terms are used by the NQF as "terms of art." (See Box B.) For the list to be used for comparative purposes within and across entities over time, changes to the definitions of these terms are likely to have a material effect on data collection and make comparative trend analyses impossible. Appendix C presents definitions for other terms, including terms that do not require as rigorous standardization as those found in Box B, but whose use is recommended. Besides terminology, additional detailed specifications may need to be developed during pilot tests for some of the events to ensure standardized data collection.

Box B – Definitions of Key Terms

Associated with means that it is reasonable to initially assume that the adverse event was due to the referenced course of care; further investigation and/or root cause analysis of the unplanned event may be needed to confirm or refute the presumed relationship.

Disability means a physical or mental impairment that substantially limits one or more of the major life activities of an individual.

Healthcare facility means any licensed facility that is organized, maintained, and operated for the diagnosis, prevention, treatment, rehabilitation, convalescence, or other care of human illness or injury, physical or mental, including care during and after pregnancy. Healthcare facilities include, but are not limited to, hospitals, nursing homes, rehabilitation centers, medical centers or offices, outpatient dialysis centers, reproductive health centers, independent clinical laboratories, hospices, and ambulatory surgical centers.

This includes distinguishing between whether the information that is collected is aggregated or identifiable by institution and/or provider.

Implementation and Reporting Issues

The Institute of Medicine's (IOM) report, *To Err Is Human,* recommended a nationwide mandatory reporting system involving the collection by state governments of standardized information about adverse events that result in death or serious harm.[1] Although the IOM recommendation continues to be controversial, a number of states have already implemented or are considering implementing such reporting systems. The federal government has also indicated its intent to support pilot tests of healthcare adverse event reporting systems.[3]

Standardization

Accurate assessment of information from medical error reporting systems within and across states requires that concepts be clearly defined and measures of these events be consistently applied. Since there are currently no nationwide, standardized definitions and measures of serious reportable events, there is no clear agreement on appropriate ways to apply such measures within state-based reporting systems. The NQF's *Serious Reportable Events in Healthcare* report attempts to remedy this problem.

In this report, the NQF has identified a list of serious reportable events in healthcare using standardized definitions and reflecting the consensus of diverse healthcare stakeholders. Appropriately implemented, the list should enable standardized data collection and reporting of such events within and across states and thereby should be an important initial step for addressing these types of healthcare errors.

The NQF's standardized list of serious adverse events is a resource for states that develop reporting systems or adapt existing systems. The list does not limit a state's ability to

[3] *Doing What Counts for Patient Safety: Federal Action to Reduce Medical Errors and Their Impact, Report of the Quality Interagency Coordination Task Force (QuIC) to the President.* Washington, DC: U.S. Government Printing Office; February 2000.

Table 1 – List of Serious Reportable Events

EVENT	ADDITIONAL SPECIFICATIONS
1. SURGICAL EVENTS	
A. Surgery performed on the wrong body part	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
B. Surgery performed on the wrong patient	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures.
C. Wrong surgical procedure performed on a patient	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
D. Retention of a foreign object in a patient after surgery or other procedure	Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
E. Intraoperative or immediately post-operative death in an ASA Class I patient	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.
2. PRODUCT OR DEVICE EVENTS	
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
3. PATIENT PROTECTION EVENTS	
A. Infant discharged to the wrong person	
B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	Excludes events involving competent adults.
C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.

Table 1 – List of Serious Reportable Events (continued)

EVENT	ADDITIONAL SPECIFICATIONS
4. CARE MANAGEMENT EVENTS	
A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)	Excludes reasonable differences in clinical judgment on drug selection and dose.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia in neonates	Hyperbilirubinimia is defined as bilirubin levels >30 mg/dl. Neonates refers to the first 28 days of life.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
G. Patient death or serious disability due to spinal manipulative therapy	
5. ENVIRONMENTAL EVENTS	
A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	Excludes events involving planned treatments such as electric countershock.
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	
D. Patient death associated with a fall while being cared for in a healthcare facility	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	
6. CRIMINAL EVENTS	
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	
B. Abduction of a patient of any age	
C. Sexual assault on a patient within or on the grounds of a healthcare facility	
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility	

expand the list. However, maintaining the integrity of the definitions and specifications in the NQF consensus list is essential if the list is to be used to obtain information that is comparable within and across states. That is, if a state wishes to expand an existing event, it should do so by specifying and collecting the additional information as a separate event. Ideally, new events would only be included after a broad-based review was conducted and consensus was reached, as in the process used to develop this list.

"Accurate assessment of information from medical error reporting systems within and across states requires that concepts be clearly defined and measures of these events be consistently applied."

Specification

Additional specification of some events on the NQF list may be necessary to ensure its consistent implementation and standardized data collection. Without additional specification, the events may be interpreted and reported differently.* This issue should be addressed as part of the subsequent pilot testing and refinement process that should be undertaken by the federal government, in partnership with interested states, as follow-up to this report.

To further facilitate consistent reporting, it would be advantageous to link the events on the NQF consensus list with some type of national standardized system of codes. Two such commonly used classification systems are the International Classification of Diseases (ICD) and the Current Procedural Terminology (CPT). ICD codes serve as tools for classifying morbidity data for medical records indexing, medical care review, and compilation of health statistics; they are also used in many states to bill for hospital services. CPT codes are used to provide a uniform language that accurately describes medical, surgical, and diagnostic services, thereby serving as an effective means for reliable nationwide communication among physicians, patients, and third parties.

* For example, if a patient were injured from a device malfunction and needed to use crutches at the time of discharge, some states might interpret this to mean "serious disability," whereas other states might not. However, if the event were to be further specified such that serious disability includes all patients discharged on crutches, in a wheelchair, etc., then this would enable more consistent reporting. Without additional specification, the interpretation of what constitutes "serious disability" becomes a judgment call.

CPT codes are currently used in federal programs such as Medicare and Medicaid to code and describe healthcare services, primarily for billing purposes.[4]

If each event on the list could be linked to an ICD or CPT code, this would represent significant progress toward ensuring that events are consistently reported among states. It would also ease the burden of reporting for healthcare facilities. Currently, however, only about half of the events can be accurately reported using an existing ICD code and even fewer using an existing CPT code. Pilots should facilitate the use of new "test codes," derived from the ICD and/or CPT systems, that correlate with each event. Simultaneously, the process for reviewing and updating both sets of codes should be investigated.

Reporting

The events described in this list are intended to be reportable by all licensed healthcare facilities in states that adopt the NQF list as part of an adverse events reporting system. As noted, to achieve a national system that yields data comparable within and across states, reporting of the events must be implemented uniformly. Sophisticated information technology systems are not a prerequisite to implementing such reporting, although an interoperable, national healthcare information infrastructure would significantly ease the burden of reporting on facilities. A number of individual events on this list are elements of other public and private reporting systems, such as the U.S. Food and Drug Administration's MedWatch system for adverse events related to drugs, devices, and biologics and the U.S. Pharmacopeia's MedMarx system and National Coordinating Council for Medication Error Reporting and Prevention for drug-related adverse events. Illegal acts are reportable to the criminal justice system, and some criminal events on this list are also reportable to state licensing bodies. However, there is no national consistency in such reporting. By entrusting the reporting of events on this list to a single state agency or state-designated entity, a comprehensive state-based reporting system can evolve that complements the states' public health surveillance role. An additional benefit of a comparable reporting system is that aggregate data may be large enough for statistical analyses of very low incidence events; this would facilitate the identification of ways to further reduce the occurrence of these adverse events.

Compliance with reporting serious adverse events will depend on how the state deals with concerns about discoverability, peer review protections, and legal liability. Experience with other reporting systems tells us that avoiding accusations of blame, along with providing appropriate legal and privacy protections, will encourage reporting. Additionally, a state-based reporting system should include feedback to the individual institutions and to those designing and implementing findings from root cause analyses and other quality

[4] American Medical Association. CPT process – how a code becomes a code. Available at: *www.ama-assn.org/ama/pub/category/3882.html.*

improvement activities. Mere counting of events has no inherent value. Indeed, underlying any reporting system should be both the ability and the intent to improve the effectiveness, efficiency, and quality of healthcare services.

Reducing Burden

To reduce the reporting burden on healthcare professionals and healthcare facilities, states should institute policies that permit facilities to report an event only once to a single state entity. Other relevant state-based reporting systems (e.g., reporting to state healthcare licensing entities) should retrieve reports from the primary receiving entity, not through a duplicate report from the facility. If this is not done, states should, at minimum, enact policies that allow the same data in the same form to be filed with multiple agencies.

The federal government should similarly standardize and coordinate with states. Until a standardized reporting framework is pursued, including coordination with existing voluntary and mandatory systems, the burden on individual healthcare professionals and healthcare facilities to meet the requirements of divergent systems will be a source of frustration that wastes resources and diminishes the potential for public accountability and quality improvement.

Use of Reports Based on the List

While the intended use of the NQF's consensus list of serious reportable events is to facilitate public accountability, little will be accomplished if the response is merely to record them or if the reports are used to punish healthcare organizations. The data should be used to actually improve patient safety.

Meaningful accountability requires that both healthcare organizations and oversight agencies use the reports to improve patient safety. There are two main methods by which this can be accomplished.

First, when an event occurs, it should be investigated to determine the underlying system problems and/or failures (e.g., via a root cause analysis). The identified problem should then be corrected to prevent recurrence of the event. Prevention strategies can include identifying points in the system of care where protocols should be changed, new or different technology implemented, training revised, and/or other processes changed. These activities are the responsibility of the healthcare organization.

Second, aggregate information about serious reportable events from multiple healthcare organizations can be used to improve safety if the lessons learned from their investigations of the underlying system problems and/or failures are disseminated to other healthcare organizations. Such outreach would allow others to take appropriate measures to prevent similar events in their own institutions. Dissemination of this important information is possible if the oversight agency or its designee collects information not only about the adverse events themselves, but also about the findings from the investigations (e.g., the root cause analyses) of the events. This report does not address reporting of the findings of the investigations or issues related to such reporting,

such as standardized report formats (including classifications, nomenclature, and codes) or protection of the findings from public disclosure.

Quality Improvement Organizations

When this list of adverse events is implemented by states, healthcare facilities will have an obligation to report the occurrence of the events. The entities receiving the reports in each state (e.g., public health agencies or state licensing boards) have a reciprocal obligation to ensure that the data provided by the reports are available to the reporting institutions so that they can be used collectively to both identify problems and explore solutions. These solutions should be focused on systemic prevention strategies—identifying and addressing points in the system of care where protocols should be changed, technology implemented, training undertaken, or other systems redesigned. Use of a report to assign responsibility to an individual is rarely justified or successful in preventing future lapses if the same system features remain. Moreover, using reports to perpetuate a culture of blame will assuredly discourage reporting.[5]

Consumers and Purchasers

Information based on events that are reported should be made available to consumers and purchasers as well as providers. Each state implementing the list should determine its own specifics about how reports are to be analyzed, summarized, and disclosed to the public (i.e., whether institution-specific information versus regional summaries are made public, etc.), but failing to provide a mechanism for public availability is likely to be ill received by consumers. Of note, state-based reporting, versus a federally based national system, is likely to result in uneven implementation. Such a situation may be problematic for some large purchasers, since many employers operate across state boundaries and health plans.

[5] Bovbjerg RR, Sloan FA. A no fault for medical injury: theory and evidence. University of *Cincinnati Law Rev.* 1998;67:53-123.

While public availability of report-related data is important, so too is public education about what the data does, or does not, mean. Because most of the events in the list are likely to be rare, fair comparisons across institutions based on the rate of these events may be impossible based on current risk adjustment and statistical methods. Even multiyear comparisons will most likely not permit fair comparisons. Hence, data derived from reports of events on this list should not be interpreted as meaning that an individual institution is of better or lesser quality, nor should it alone be used for selecting an institution.

Additionally, regional population-based rates are more likely to reflect valid data, particularly for tracking trends over time. States may wish to collaborate in data analysis efforts so that regional information can be disclosed to consumers and purchasers. Institution-based rates are unlikely to be useful initially, but research to examine the statistical validity of such rates could enhance the future usefulness of the information to consumers, purchasers, and providers.

Recommendations for Research

Considering items that were not included on the list led to the identification of areas for which additional research might have overcome the shortfalls that led to exclusion of the event. Moreover, while identification of a core list of serious adverse events is an important first step, it must be followed by the development of mechanisms or models to translate the list from concept to practice.

Specifically, the following research issues should be addressed:

- exploring effective mechanisms to collect data and communicate serious reportable events to the public;
- examining how data derived from using the NQF list can be disclosed in a way that meets the public's needs, yet is balanced with the need for providers to learn from mistakes.

- testing the operational value and utility of the events on the list, including research on the necessity to support such a list and the public's perceptions of the impact of the list;
- identifying ICD, CPT, or other codes that correlate with each serious reportable event on the list;
- investigating the process for reviewing and updating ICD and/or CPT codes; and
- defining comparable risk adjustment measures when individuals' risk to experience the event is dissimilar.

Finally, the pilot tests proposed by the federal government's Quality Interagency Coordination Task Force to evaluate implementation of the list should also examine the extent to which the data drive healthcare quality improvement.[6]

Process for Updating the List

This consensus list of serious reportable events should not be considered static. At the same time, implementation of the list and pilot tests should be permitted to proceed for a period of time without being complicated by the introduction of new definitions or events. Currently, it is difficult to project when the list should be updated. It is recommended that in about 18 months, the NQF should convene a committee, subject to funding, to consider how to update the list.

Acknowledgments

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[6] *Doing What Counts for Patient Safety: Federal Action to Reduce Medical Errors and Their Impact, Report of the Quality Interagency Coordination Task Force (QuIC) to the President.* Washington, DC: U.S. Government Printing Office; February 2000.

Appendix A

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[1]Steering Committee meetings were held on December 20, 2000; February 21, 2001; March 23, 2001 (conference call); April 17, 2001; and May 4, 2001 (conference call).

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Appendix B
Steering Committee Commentary

Introduction

This project, like all National Quality Forum (NQF) activities, has involved the active participation of representatives from across the spectrum of healthcare stakeholders. This appendix summarizes the rationale and evidence supporting the recommendations of the Steering Committee, which is the first step in the NQF Consensus Process (Appendix E).

As a first step, the Steering Committee discussed the purpose of a core list of serious reportable events and established criteria for including an event on the list. The Steering Committee then identified numerous candidate events, including on the list only those that met the criteria. The Steering Committee also discussed issues of implementation and reporting.

An Ex Officio Special Advisory Panel (Appendix A) comprising state health policymakers was convened to provide the Steering Committee with states' perspectives, in particular regarding issues relating to the adoption of the list by states.

In addition to the input provided by the Ex Officio Special Advisory Panel, the Steering Committee's deliberations were informed by:

- direct input from NQF members and nonmembers during meetings of the Steering Committee;
- information from the literature, including studies on state experiences with healthcare error reporting from the National Academy for State Health Policy[1];

[1]Rosenthal J, Riley T, Booth M. *State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey*. Portland Me: National Academy of State Health Policy; April 2000.

- an informal survey of state requirements for reporting of illegal acts and acts of professional misconduct conducted by the National Association of Health Data Organizations[2] and supplemented with information NQF obtained directly from states; and
- substantial input solicited by the NQF from its member organizations, as well as from other organizations having expertise in the areas of specific candidate events.

Purpose of the List

As noted in the report, this project is intended to enable the development of a consistent and reliable state-based national healthcare error reporting system. Standardized reporting about these events would begin to address the dearth of information about healthcare errors and unintended adverse events. The Steering Committee is aware that U.S. Agency for Healthcare Research and Quality intends to use the list for state-based pilot test(s) and encourages the rapid deployment of such projects.

The Steering Committee noted that it is well established that the current lack of data stems from the fact that reporting a healthcare error is widely believed to invite blame and legal liability on the part of the caregiver or institution involved, without leading to any positive changes in the system of care that might prevent the same error from occuring again.[3] From the perspective of the provider, there is no perceived benefit to reporting even serious errors and significant reason to not do so. As a result, there exists neither data to support providers' efforts to improve the system of care, nor data to allow consumers, purchasers, or policymakers to assess the quality of care and motivate improvements.

The void in information about healthcare errors useful to providers and consumers does not result from a lack of attempts to collect such data. According to the National Academy of State Health Policy, 15 states require hospitals to report at least some kinds of adverse events related to healthcare, and 6 states have voluntary reporting systems.[1]

Notable national reporting efforts also exist, and the Steering Committee discussed these during its deliberations. For example, the U.S. Food and Drug Administration (FDA) MedWatch program receives reports of adverse events related to the use of drugs, biologics, and devices that are voluntarily submitted by providers and the public through its MedWatch program, and the U.S. Centers for Disease Control and Prevention collects data on hospital-acquired infections, a very common unintended adverse event. In the private sector, the Joint Commission on Accreditation of Healthcare Organizations operates a "Sentinel Event" reporting program, ECRI maintains a database based on voluntary

[2] Love D. Executive Director, National Association of Health Data Organizations, Salt Lake City, Utah. *Letter to the National Quality Forum*; January 24, 2001.

[3] Kohn LT, Corrigan JM, Donaldson MD, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

reporting of medical device-related errors and problems, and both the U.S. Pharmacopeia and Institute for Safe Medication Practices maintain a database of voluntarily reported medication errors, which are also shared with FDA. These efforts are clearly important and provide vital information to the organizations that sponsor them – e.g., FDA analyzes MedWatch data to determine whether a particular drug poses a previously unrecognized risk of side effects. Nevertheless, existing reporting systems suffer from three major problems:

- Severe underreporting. Most reporting systems are voluntary, and there are few incentives and significant disincentives at work. Often, an individual may not even know whether an error or event should be reported, or to whom. Even states with mandatory reporting systems have serious underreporting due, at least in part, to providers' belief that reporting will only bring investigation and punishment.
- Lack of comparability. No standardized nomenclature or breadth of required elements and/or events exists. Existing reporting efforts generally focus on only a few types of errors and events, and each focuses on different ones. Even where the general information sought is similar, the data are largely not comparable due to differences in definitions and data specifications.
- Lack of information sharing and feedback. States generally cannot find out what errors in their locales have been reported to national reporting systems, and consumers or purchasers cannot learn about adverse events in their communities. Even health professionals and institutions reporting the data usually cannot learn what errors or events have occurred (let alone which are common) in their own peer group, which decreases the ability to monitor performance and make improvements.

In the context of the problems with current reporting systems, the Steering Committee considered the purpose of a state-based reporting system that would be based on a list of events endorsed by the NQF, since the purpose would affect the design of the list and the criteria by which candidate events for the list would be judged. Specifically:

- Should the primary purpose of the list be to support hospitals' internal quality improvement efforts? If so, the list might focus on common, high-frequency patient injuries and be designed around data collection that is intrinsic to the provision of care.
- Alternatively, should the primary purpose of the list be for public accountability to enable the public, or entities acting on their behalf, to monitor the incidence of errors or adverse events of particular interest or concern to the public? If so, the list might be designed to place more emphasis on serious events, such as patient deaths resulting from errors.

After considering the draft framework being discussed by the NQF's Strategic Framework Board and the links between measurement for internal improvement and measurement for accountability and selection of providers, the Steering Committee concluded that the primary purpose of the list of serious reportable

events should be public accountability but also, importantly, that the reports acquired using this list should be used to facilitate systematic quality improvement. Furthermore, the Steering Committee concluded that public accountability does not itself imply that the information gathered for this purpose can be usable for selection of providers. It does imply an obligation to use the data to motivate and support improvements through information sharing and feedback to healthcare providers.

The usefulness of the data for quality improvement also depends on adequate resources for monitoring and improvement interventions. Without prioritizing resources for this function, the value of the data will be diminished. Furthermore, the commitment to translate the data for public accountability must be approached with the consideration of building consumer trust in the healthcare system.

Criteria for Inclusion of Events on the List

Because the Steering Committee defined the primary purpose of the list as public accountability, it agreed that the seriousness of an event, particularly the level of harm actually resulting to the patient, was of primary importance. Hence, the Steering Committee spent considerable time debating an appropriate definition of "serious" and applied the criterion in such a way that events involving death or disability to the patient received especially great attention. However, the Steering Committee also felt that some events, when they occur, so strongly indicate a high risk of potential harm that they should be reported even if the actual harm to a particular patient is not serious. Surgery performed on the wrong patient, for example, was deemed to meet this criterion, even if the surgery did not result in the death or disability of the patient.

Since reports, at a minimum in aggregated and de-identified form, likely would be available to state agencies and could be made available to the general public to demonstrate public accountability, the Steering Committee also concluded that events on the list must be unambiguous to reduce disincentives for reporting as well as the confusion about whether an event should be reported. The ability to clearly define, quantify, and audit events were all considered as separate criteria. The Steering Committee ultimately decided that all of these concepts were captured by the term "unambiguous," which was defined to encompass these concepts.

The distinction between "unintended" and "preventable" a criterion for events to include on the list was debated at length. "Unintended" was considered to be less associated with the implication that someone was to blame for an event and also was considered to have the advantage of capturing events that, upon analysis, suggest methods of prevention that would otherwise be unknown. On the other hand, there was concern that many unintended events are truly not preventable given current knowledge, and reporting such events to an external body, particularly if the data were eventually summarized for

the public, would lead to misunderstanding. Ultimately the Steering Committee agreed that "preventable" was the more relevant concept for the intended purpose, but because few classes of events are always preventable, the Steering Committee concluded that an event be judged "usually preventable" to qualify for the list.

Evidence for the Preventablility of Events on the List

The Steering Committee stressed that if public accountability is to motivate caregivers to improve, they must know how to improve. Thus, at a minimum, evidence or formal expert opinion on strategies that providers can implement to reduce the risk of these adverse events should exist. Evidence-based guidelines provide systematically developed advice for healthcare professionals on the implementation of clinical practices such as those for the prevention of wrong-site surgery or pressure ulcers. In addition to guidelines, the medical literature reveals many strategies or practices that could be used to prevent the events on the list.

Abundant literature exists, for example, on how to prevent medication errors related to dose, drug, patient, time, or route of administration. Computer order entry, color-coding of packaging, 24-hour availability of a pharmacist to intensive care units and emergency departments, and the restriction of verbal orders are among the well-documented strategies that can be used to prevent these events. Criminal events were likewise viewed by the Steering Committee as preventable. For example, while a healthcare facility cannot eliminate all risk of physical assault, the facility can undertake numerous preventive measures to reduce that risk.

An exhaustive review of the literature on the preventability of all the events on the list was beyond the scope of this project. The Steering Committee is aware, however, that many of the salient techniques that are applicable to the prevention of events on its proposed list may be included in a separate NQF project to compile a set of core "safe practices" for patient safety.

Events or Specifications Considered but Not Included

The Steering Committee considered a number of events that ultimately were not included on the list recommended to the NQF membership. Exclusion resulted primarily because an event met some, but not all, of the Steering Committee's criteria for inclusion. Specifically:

- "Intra-operative patient death during elective surgery" was not included because it was replaced by the more unambiguous intraoperative or immediately post-operative death in an ASA Class I patient.
- "Death, disability, or material change in treatment resulting from or substantially due to the loss, misplacement, destruction and/or failure to communicate diagnostic test results to the patient" was not included. The Steering Committee was unable to identify specifications to differentiate between serious and non-serious failures.

- "Patient death from a hospital-acquired (nosocomial) infection" was excluded. The Steering Committee concluded that there was insufficient evidence on the preventability of many of these infections and further agreed that the issue of risk adjustment would complicate reporting of this event.
- "Failure to treat a patient according to accepted standards of practice" (e.g., not providing appropriate therapies to a patient with acute coronary syndrome; failing to treat sexually transmitted diseases; not monitoring blood sugar in a diabetic patient undergoing surgery; or failing to offer immunizations to a child or infant) was eliminated because acts of omission of these types did not have sufficient specification, although an event merely being an act of omission was not a criterion per se for exclusion.
- "Any act by a caregiver that reflects gross negligence, malfeasance, reprehensible ignorance, or criminal intent" was excluded because agreement was not reached on how to define the key terms and whether the criterion that it was unambiguous could be determined outside the legal context.
- "Any other patient death or serious injury/illness not anticipated in the normal course of events and believed to be due to the processes of care" was excluded from the list because the Steering Committee believed identifying such an event was too difficult to operationalize.

Note that the Steering Committee deliberated specifically about a written request that event 4C, "maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility" (with additional specifications; see Table 1), be deleted from the list. The Steering Committee felt that the event, as defined and in particular further specified, clearly met the criteria and was also quite important for public credibility – as recognized by the fact that most states currently require mandatory reporting of maternal deaths associated with labor and delivery.

Research

At several junctures during the Steering Committee's deliberations – e.g., as the purpose of the list was contemplated, as events were excluded, and as reporting systems were considered – the Steering Committee identified specific gaps in the current knowledge base that would benefit from research. In making these recommendations in the report, the Steering Committee emphasizes that the list is not all inclusive. Rather, the focus is on priority research areas that would advance or improve identifying and reporting serious adverse events and/or implementing the proposed list.

Appendix C
Glossary

The following terms are defined as they apply to the NQF's list of serious reportable events.

Adverse describes a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.

ASA (American Society of Anesthesiologists) Class I patient refers to a normal, healthy patient, i.e., one who has no organic, physiologic, biochemical, or psychiatric disturbance. The pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

Associated with means that it is reasonable to assume initially that the adverse event was due to the referenced course of care; the unplanned event may be subject to further investigation and/or root cause analysis in order to confirm or refute the presumed relationship.

Biologics refers to therapeutics and products, including blood and vaccines, derived from living sources (such as humans, animals, and microorganisms).

Device refers to an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, which is recognized in the official National Formulary, the U.S. Pharmacopeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or intended to affect the structure or any function; and that does not achieve any of its primary intended purposes through chemical action and that is not dependent upon being metabolized for the achievement of any of its primary intended purposes. This includes items such as sutures, prepackaged procedure kits, laerdal defibrillators, pacemakers, contact lenses, etc.

Disability means a physical or mental impairment that substantially limits one or more of the major life activities of an individual.

Electrocution is death by electric shock.

Error is the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).

Event means a discrete, auditable, and clearly defined occurrence.

Healthcare facility means any licensed facility that is organized, maintained, and operated for the diagnosis, prevention, treatment, rehabilitation, convalescence, or other care of human illness or injury, physical or mental, including care during and after pregnancy. Healthcare facilities include hospitals, nursing homes, rehabilitation centers, reproductive health centers, independent clinical laboratories, hospices, and ambulatory surgical centers.

Hypoglycemia is a physiologic state in which the blood sugar falls below 60 mg/dl and physiological and/or neurological dysfunction begins.

Intended use is the use of a device as described on the label and associated materials provided by the device's manufacturers.

Kernicterus refers to the medical condition in which elevated levels of bilirubin cause brain damage.

Low-risk pregnancy refers to a woman aged 18-39, with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.

Patient elopement refers to any situation in which an admitted patient (i.e., inpatient) leaves the healthcare facility without staff being aware that the patient has done so.

Preventable describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure.

Public accountability is the obligation or duty of specific individuals and/or institutions to make information about their actions or performance available to the public or a public organization or agency (or its designee) that has responsibility for oversight and is answerable to the general public.

Serious describes an event that results in death or loss of a body part or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from an inpatient healthcare facility or, when referring to other than an adverse event, an event whose occurrence is grave.

Spinal manipulative therapy encompasses all types of manual techniques, including spinal mobilization (movement of a joint within its physiologic range of motion) and manipulation (movement beyond its physiologic range of motion), regardless of their precise anatomic and physiologic focus or their discipline of origin.

Toxic substance refers to chemicals that are present in sufficient concentration to pose a hazard to human health.

Unambiguous refers to an event that is clearly defined and easily identified.

The National Quality Forum

Appendix D

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March of Dimes
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Provider and Health Plan Council

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National Association of Children's Hospitals and Related Institutions
National Association of Public Hospitals and Health Systems
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*As of July 2001, when the NQF Consensus Development Process for this report was initiated.

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American Board of Internal Medicine
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Appendix E

Consensus Development Process: Summary

The National Quality Forum (NQF) is a voluntary consensus standards organization. The NQF brings together diverse healthcare stakeholders to develop consensus on core measures of healthcare quality. The primary participants in the NQF consensus process are NQF member organizations. These include:

- consumer and patient groups;
- health care purchasers;
- health care providers and health plans; and
- research and quality improvement organizations.

Any organization interested in healthcare quality measurement and improvement can apply to be a member of the NQF. Membership information is available on the NQF website.

Members of the public with particular expertise in a given topic may also be invited to participate in the early identification of draft standards as technical advisors or Steering Committee members. In addition, the NQF consensus process explicitly recognizes a role for the general public to comment on draft standards and to appeal quality measurement standards adopted by the NQF. Information on NQF projects, including information on NQF meetings open to the public, is posted on the NQF website *(www.qualityforum.org)*.

Each project the NQF undertakes is guided by a Steering Committee (or Review Committee) composed of individuals from each of the four critical stakeholder perspectives. With the assistance of NQF staff and technical advisory panels and the ongoing input of other NQF members, a Steering Committee conducts an overall assessment

of the state of the field in the particular topic area and recommends a set of draft measures, indicators, or practices for review, along with the rationale for selecting them. The recommended measure set is distributed for review and comment, first to NQF members and then to the general public.

Following the comment period, a revised product is distributed to NQF Members for voting. The vote need not be unanimous within or across all Member Councils for consensus to be achieved. If a majority of members within each Council do not vote approval, staff attempt to reconcile differences among members to maximize agreement a second round of voting is conducted. Proposed products that have undergone this process and have been approved by at least two Member Councils after the second round of voting are forwarded to the NQF Board of Directors for consideration. All products must be approved by a vote of the NQF Board.

Affected parties may appeal standards approved by the NQF Board of Directors. Once a measure set has been approved, the federal government may utilize the information for standardization purposes in accordance with the provisions of the National Technology Transfer Advancement Act of 1995 (P.L. 104-113) and the Office of Management and Budget Circular A-119.

Standards are updated as warranted.

For this report, the NQF Consensus Process, version 1.3 was in effect. The complete process can be found at *www.qualityforum.org*.

The National Quality Forum

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